U.S. Food and Drug Administration Approves SIGA Technologies' TPOXX® (tecovirimat) for the Treatment of Smallpox

July 13, 2018

- First therapy specifically approved for smallpox advances health security against a significant bioterror threat-
- Company Granted Priority Review Voucher -

NEW YORK, July 13, 2018 (GLOBE NEWSWIRE) -- SIGA Technologies, Inc. (SIGA) (NASDAQ:SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that the U.S. Food and Drug Administration (FDA) has approved oral TPOXX® (tecovirimat) for the treatment of smallpox to mitigate the impact of a potential outbreak. TPOXX, a small-molecule antiviral treatment for smallpox, is the first therapy specifically approved for this indication. On May 1, 2018, the FDA's Antimicrobial Drugs Advisory Committee voted unanimously, 17 to 0, that the benefits of TPOXX outweigh its risks.

Concurrent with the approval, FDA granted SIGA's request for a Priority Review Voucher (PRV). A PRV is a voucher that may be used to obtain an accelerated FDA review of a future SIGA product, or sold to a third party, and this is the first PRV awarded under the Material Threat Countermeasure PRV program enacted by the 2016 21st Century Cures Act. In addition, FDA approved a seven-year expiry for TPOXX. Under SIGA's existing contract with the Biomedical Advanced Research and Development Authority (BARDA), the company will ask BARDA to exercise an option for a $50 million payment to the company based on this extended shelf-life determination. The exercise of this option is at the sole discretion of BARDA.

With the approval, SIGA is entitled to a $41 million hold back payment under the existing contract with BARDA, provided that BARDA confirms that there is no difference between the approved product and the courses of TPOXX that have already been delivered to the Strategic National Stockpile (SNS).

FDA approval is based on data from 12 clinical trials of oral TPOXX in over 700 healthy human volunteers, which showed no drug-related serious adverse events. Four pivotal trials in non-human primates (NHPs) and two pivotal trials in rabbits demonstrated that TPOXX significantly reduced both mortality and viral load in NHP infected with monkeypox virus (MPXV) and in rabbits infected with rabbitpox virus. The results of these studies were published in the July 5, 2018 issue of the *New England Journal of Medicine*.

"TPOXX is proof that public-private partnerships work when the partners are committed to a focused mission," said Dr. Phil Gomez, Chief Executive Officer of SIGA Technologies, Inc. "The FDA approval of TPOXX achieves an important objective for both SIGA and our lead partner in the U.S. Government, the Biomedical Advanced Research and Development Authority (BARDA). The approval validates this novel smallpox therapy as an important medical countermeasure in response to a potential smallpox outbreak."

"We would like to acknowledge the efforts by everyone at SIGA and our many partners who have contributed to the development and approval of TPOXX," added Dennis Hruby, PhD, Chief Scientific Officer of SIGA Technologies, Inc. "These partners include BARDA, the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, the Department of Defense (including the Defense Threat Reduction Agency and the U.S. Army Medical Research Institute of Infectious Diseases), our academic and clinical collaborators, and our colleagues at the FDA."

TPOXX will be available initially only through the U.S. government's Strategic National Stockpile (SNS). SIGA has a $472 million procurement and development contract with BARDA, as part of which 2 million courses of oral TPOXX have been delivered to the SNS. Currently, there is a Request for Proposal outstanding for the maintenance of a smallpox antiviral stockpile within the SNS. SIGA intends to explore additional markets and potential indications for TPOXX in the United States and around the world.

During the May 1, 2018 FDA Advisory committee, several members of the committee also suggested that there could be benefit in exploring additional indications post-FDA approval, including prophylactic use in individuals exposed to smallpox and other orthopoxviruses, such as monkeypox, which also infects humans. Committee members cited the likely use of TPOXX in the post-exposure prophylaxis setting in the event of a smallpox outbreak and a 15-20% mortality rate in people infected with monkeypox. SIGA will examine these potential markets and the feasibility of expanding the TPOXX label to include these indications.

Smallpox remains a significant bioterrorism threat, and the U.S. government has been focused on the development of medical countermeasures to mitigate that threat. Vaccines are an important component of a response to a smallpox outbreak, but the availability of a therapeutic such as TPOXX is critical to reduce the morbidity and mortality of such an outbreak. The risk of a smallpox outbreak is a global risk with far-reaching consequences. As such, the U.S. FDA approval is an important milestone in highlighting for international governments the safety and efficacy of TPOXX for treatment of smallpox.

TPOXX's advanced development has been funded in partnership with BARDA.

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a commercial-stage pharmaceutical company focused on the health security market. Health security comprises countermeasures for biological, chemical, radiological and nuclear attacks (biodefense market), vaccines and therapies for emerging infectious diseases, and health preparedness. Our lead product is TPOXX®, also known as tecovirimat and ST-246®, an orally administered and IV formulation antiviral drug for the treatment of human smallpox disease caused by variola virus. TPOXX is a novel small-molecule drug of which 2 million courses have been delivered to the Strategic National Stockpile under Project BioShield. For more information about SIGA, please visit www.siga.com.

About Smallpox[1]

Smallpox is a contagious, disfiguring and often deadly disease that has affected humans for thousands of years. Naturally-occurring smallpox was eradicated worldwide by 1980, the result of an unprecedented global immunization campaign. Samples of smallpox virus have been kept for research purposes. This has led to concerns that smallpox could someday be used as a biological warfare agent. No cure or treatment for smallpox exists. A vaccine can prevent smallpox, but the risk of the vaccine's side effects is too high to justify routine vaccination for people at low risk of exposure to the smallpox virus.

FORWARD-LOOKING STATEMENTS

This press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements relating to the submission and approval of TPOXX® by the FDA. Such forward-looking statements are subject to various known and unknown risks and uncertainties, and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this press release, is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and in other documents that SIGA has filed with the SEC. SIGA urges investors and security holders to read those documents free of charge at the SEC's web site at http://www.sec.gov. Interested parties may also obtain those documents free of charge from SIGA. Forward-looking statements are current only as of the date on which such statements were made, and except for our ongoing obligations under the United States of America federal securities laws, we undertake no obligation to update publicly any forward-looking statements whether as a result of new information, future events, or otherwise.

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[1] http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769

Source: SIGA Technologies Inc.